



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of )  
Doddabele L. Madhavi )  
Serial No. 10/735,335 )  
Filed: December 12, 2003 )  
For: Bioavailable Carotenoid-Cyclodextrin )  
Formulations For Soft-Gels and Other )  
Encapsulation Systems )

COMMISSIONER OF PATENTS AND TRADEMARKS  
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**INFORMATION DISCLOSURE STATEMENT**

Sir:

This Information Disclosure Statement is filed in conformity with 37 C.F.R. §§1.56 and 1.97. Accordingly, copies of the art cited herein are provided:

<u>U.S. Pat. No.</u>	<u>Date</u>	<u>Name</u>
5,384,186	01-24-1995	Trinh, et al.

Publications

SKALKO-BASNET, et al., "Liposomes Containing Drug and Cyclodextrin Prepared by the One-Step Spray-Drying Method", Drug Dev Ind Pharm. 2000 Dec;26(12):1279-84.

YU, et al., "Effect of camphor/cyclodextrin complexation on the stability of O/W/O multiple emulsions", Int J Pharm 2003 Aug 11;261(1-2):1-8.

VALERO, et al., "Ternary naproxen: beta-cyclodextrin:polyethylene glycol complex formation", Int J Pharm 2003 Oct 20; 265(1-2):141-9.

VEIGA, et al., "Influence of surfactants (present in the dissolution media) on the release behaviour of tolbutamide from its inclusion complex with beta-cyclodextrin", Eur J. Pharm Sci. 2000 Jan;9(3):291-9.

TONNESEN, et al., "Studies of curcumin and curcuminoids, XXVII. Cyclodextrin complexation: solubility, chemical and photochemical stability", Int J Pharm. 2002 Sep 5;244(1-2):127-35.

MURA, et al., "Effects of the host cavity size and the preparation method on the physicochemical properties of ibuprofen-cyclodextrin systems", Drug Dev Ind Pharm. 1999 Mar;25(3):279-87.

ALEXANDER, et al., "Chiral discrimination in cyclodextrin complexes of amino acid derivatives: beta-cyclodextrin/N-acetyl-L-phenylalanine and N-acetyl-D-

phenylalanine complex", Proc Natl Acad Sci USA. 2002 Apr 16;99 (8) :5115-20. Epub 2002 Apr 09.

VAKILY, et al., "Inclusion complexation of heptakis (2, 6-di-O-ethyl)-beta-cyclodextrin with tiaprofenic acid: pharmacokinetic consequences of a pH-dependent release and sterospecific dissolution", J Pharm Sci. 1995 Aug;84 (8) :1014-9.

MURA, et al., "Influence of the Preparation Method on the Physicochemical Properties of Binary Systems of Econazole with Cyclodextrins", Int Journ of Pharm 193 (1999) 85-95

AHSAN, et al., "Mutual Inhibition of the Insulin Absorption-Enhancing Properties of Dodecylmaltoside and Dimethyl-B-Cyclodextrin Following Nasal Administration", Pharm Res 2001 May;18 (5) : 608-14.

LOCKWOOD, et al., "Improved Aqueous Solubility of Crystalline Astaxanthin (3,3'-dihydroxy-6,6'-B, B-carotene - 4,4"-dione) by Captisol (Sulfobutyl Ether B-Cyclodextrin)", Jour of Pharm Sci, Vol 92, 922-926 (2003).

SPIRICHEV, et al., "[Study of bioavailability of different forms of synthetic beta-carotene in volunteers]", Vop Pitan. 1996(6) :22-6. Article in Russian.

MIYAKE, et al., "Improvement of solubility and oral bioavailability of rutin by complexation with 2-hydroxypropyl-beta-cyclodextrin", Pharm Dev Technol 2000;5(3) :399-407.

### REMARKS

It respectfully is submitted that none of the foregoing art, alone or in combination, shows or proposes the present invention. Accordingly, favorable action on the application respectfully is requested.

Respectfully submitted,


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Jerry K. Mueller, Jr.  
Reg. No. 27,576  
MUELLER AND SMITH, L.P.A.  
MUELLER-SMITH BUILDING  
7700 Rivers Edge Drive  
Columbus, Ohio 432351355  
(614) 436-0600  
email: smueller@muellersmith.com

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Attorney Docket No.: BIO 2-016

  
Jane Keeney

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Application Number	10/735,335
Filing Date	December 12, 2003
First Named Inventor	Doddabele L.Madhavi
Art Unit	1623
Examiner Name	Matthew L. Fedowitz
Attorney Docket Number	BIO 2-016

## U. S. PATENT DOCUMENTS

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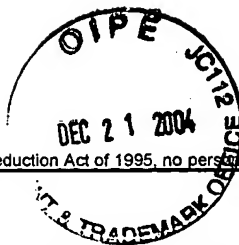
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**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	1.	SKALKO-BASNET, et al., "Influence of Surfactants (Present in the Dissolution Media) on the Release Behaviour of Tolbutamide from its Inclusion Complex with B-Cyclodextrin", Eu	
	2.	YU, et al., "Effect of camphor/cyclodextrin complexation on the stability of O/W/O multiple emulsions", Int J Pharm 2003 Aug 11;261(1-2):1-8.	
	3.	VALERO, et al., "Ternary naproxen: beta-cyclodextrin:polyethylene glycol complex formation", Int J Pharm 2003 Oct 20; 265(1-2):141-9.	
	4.	VEIGA, et al., "Influence of surfactants (present in the dissolution media) on the release behaviour of tolbutamide from its inclusion complex with beta-cyclodextrin", Eur J.	
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	6.	MURA, et al., "Effects of the host cavity size and the preparation method on the physicochemical properties of ibuprofen-cyclodextrin systems", Drug Dev Ind Pharm. 1999 Mar;25(	
	7.	ALEXANDER, et al., "Chiral discrimination in cyclodextrin complexes of amino acid derivatives: beta-cyclodextrin/N-acetyl-L-phenylalanine and N-acetyl-D-phenylalanine complex	
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	<b>Examiner Name</b>	Matthew L. Fedowitz
	<b>Attorney Docket Number</b>	BIO 2-016

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